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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Carbadox

AGENCY: Food and Drug Administration, HHS

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer Animal Health, Inc. The supplemental NADA provides for the establishment of a 42-day slaughter withdrawal period for use of carbadox in swine feed.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register,)**

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301–594–1652.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, is sponsor of NADA 4 1–061 that provides for the use of Mecadox® 10 (carbadox) Type A medicated article used to make Type B and Type C medicated swine feeds. Mecadox® is indicated for the control of bacterial swine enteritis, increased rate of weight gain, and improved feed efficiency. The sponsor filed a supplemental NADA that provides for the establishment of a withdrawal period of 42 days in swine and a limitation against use in pregnant swine or swine intended for breeding purposes. The supplemental NADA is approved as of October 5, 1998, and the regulations are amended in 21 CFR 558.115(d)(I)(ii) and (d)(2)(ii) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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[n accordance with the freedom of information provisions of 21CFR part 20 and 514.110, a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rrn. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(2)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore. under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.115 is amended by revising paragraphs (d)(1)(ii) and (d)(2)(ii) to read as follows:

$558.115 Carbadox.

* * * * *

(d) * *

(1) * * *

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

(2) * * *

(ii) *Limitations.* Not for usc in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

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Dated: Oct 25, 1998

October 25, 1998

Margaret Ann Miller
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Dot, 98-?’??? Filed ??-??-98; 8:45am]

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